

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Jong-Soo Woo et al.) Group Art Unit: 1614
Serial No.: 10/650,931) Examiner: SPIVACK, PHYLLIS G
Filed: August 27, 2003)

For: SUSTAINED RELEASE COMPOSITION FOR ORAL ADMINISTRATION
OF
DRUGS

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

Sir:

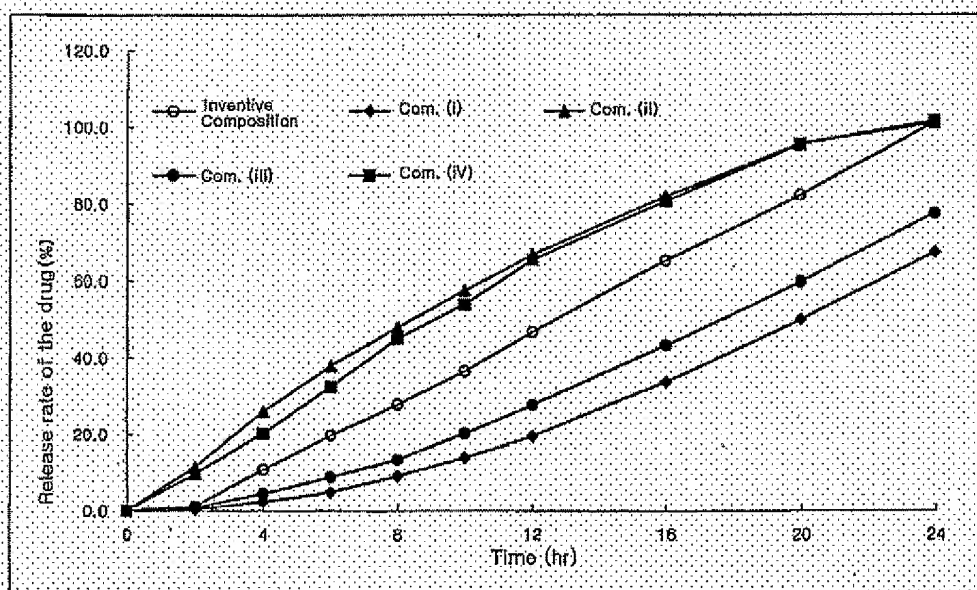
I, Jong-Soo Woo, being a citizen of the Republic of Korea and presently residing at Cheoncheonjugong Apt. 118-203, #333, Cheoncheon-dong, Jangan-gu, Suwon-si, Kyungki-do, 440-330, Republic of Korea, do declare:

That I am one of the co-inventors of the invention disclosed in the above-identified application, and hence am fully familiar with the subject matter therein; and

That I have conducted experiments to demonstrate the effect of the inventive composition having the specific relative amounts of its components, in accordance with the method of Test Example 1 of the subject application using the compositions listed in Table 1 below, wherein the comparative compositions have the components in relative amounts which are beyond the ranges defined in the present invention. The time-dependent changes in the release rate of nifedipine are shown below.

Table 1

Component		Inventive composition	Comparative composition			
			Com. (I)	Com. (II)	Com. (III)	Com. (IV)
Drug	Nifedipine	33	33	33	33	33
Carrier for sustained release	Sodium Alginate (SA)	70	300	75	15	70
	Xanthan Gum (XG)	150	750	150	205	150
Gel hydration accelerator	Hydroxypropyl methylcellulose (HPMC)	25	10	250	25	10
	Propylene glycol alginate (PG)	140	10	250	140	225
Ratio of drug : carrier : gel hydration accelerator (1:3~30:0.1~15 in the present invention)		1:6.7:5.0	1:31.8:0.6	1:6.8:15.2	1:6.7:5.0	1:6.7:7.1
Ratio of SA : XG in the carrier (1:0.1~10 in the present invention)		1:2.1	1:2.5	1:2	1:13.6	1:2.1
Ratio of HPMC : PG in the gel hydration accelerator (1:0.05~20 in the present invention)		1:5.6	1:1	1:1	1:5.6	1:22.5



As can be seen from the results above, the inventive composition exhibits a zero order release pattern while the comparative compositions which do not satisfy claimed ranges of the present invention do not exhibit a zero order release pattern.

I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and, further, that these statements made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of Unites States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Further the deponent saith not.

Date: 7th day of June, 2007

J. S. Woo

(Jong-Soo Woo)